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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,615	02/08/2001	Kaname Nakahara	216208US0XPCT	8496

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 03/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/762,615	NAKAHARA ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2002 (paper no.14)* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-9,19,20 and 32-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-9,19,20 and 32-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the Application

Acknowledgement is made of the receipt of the Declaration (37 C.F.R.1.132) and the Amendment, both filed 12/16/02 and the Change of Address filed 12/19/02.

Claims 1, 4-9, 19, 20 and 32-37 are pending. New claim 37 has been added by virtue of the amendment. Claims 1, 4-9, 19, 20 and 32-37 are rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-6, 19, 20 and 32-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Pfister *et al.* (US Pat. No.5, 232,702), (collectively, "Pfister").

Pfister et al. disclose a silicone pressure-sensitive adhesive transdermal drug delivery patch comprising a minimum of five layers which comprise a support body, a liquid reservoir layer for storing medicaments, a rate controlling membrane, a pressure sensitive adhesive layer and a release liner wherein the transdermal patch includes

various drugs, such as cardiovascular agents and anti-anginal agents (see reference column 8, lines 28-68); (column 9, lines 1-23) and Figs. 3 and 4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4-9, 19, 20 and 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfister *et al.* (US Pat. No.5, 232,702) in view of Mantelle (US Pat. No.5,446,070).

Pfister et al. as discussed above, teaches a silicone pressure-sensitive adhesive transdermal drug delivery patch comprising a minimum of five layers which comprise a

support body, a liquid reservoir layer for storing medicaments, a rate controlling membrane, pressure sensitive adhesive and a release liner wherein the transdermal patch includes various drugs, such as cardiovascular agents and anti-anginal agents (see reference column 8, lines 28-68); (column 9, lines 1-23) and Figs. 3 and 4.

Pfister teaches that the transdermal delivery device, as seen in Fig. 3, includes a minimum of five layers, wherein the first layer is a backing substrate, the second layer includes a liquid reservoir which may contain bioactive agents, drugs, excipients, enhancers, co-solvents or mixtures thereof. The reservoir-type transdermal device may include drugs selected from cardiovascular agents, anti-anginal agents, anti-arrythmic agents, etc and mixtures thereof. Also included are enhancers, excipients selected from the group consisting of polyols, surfactants, fatty acid esters, etc. The third layer is a rate controlling membrane, which acts as the rate controlling mechanism for the delivery of the liquid drug(s), co-solvents, enhancers and excipients from the reservoir. The fourth layer is a pressure sensitive adhesive and the fifth layer is a silicone pressure sensitive adhesive release liner (col. 8, lines 35-62).

Pfister does not explicitly teach the properties of water-vapor permeability of 100-g/m square or more at 40^0 C and 24 hours for the adhesive. However, it would have been deemed obvious to one of ordinary skill in the art at the time the invention was made that suitable vapor permeability ranges could be determined through routine or manipulative experimentation and in addition, since the materials used by Pfister et al. are the same, they would also provide for similar properties and results as the claimed invention.

Pfister, is deficient also in the sense that he does not explicitly teach nicorandil in the formulation.

Mantelle teaches compositions and methods for the administration of pharmaceutically active agents, wherein the composition is in the form of a bioadhesive suitable for a variety of drugs, such as anti-anginal agents, cardiotonic drugs, such as dopamine and vasodilators, such as nicorandil (see reference column 4, lines 25-44); (col. 12, lines 10-15); (col. 41, lines 9-20).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Mantelle within the teachings of Pfister because Mantelle teaches a bioadhesive composition with the incorporation of various drugs, which include anti-anginal agents, cardiotonic drugs, such as dopamine and vasodilators, such as nicorandil in the formulation and Pfister explicitly teaches the use of cardiovascular and anti-anginal agents in his transdermal preparation. The expected result would be an improved and highly effective bioadhesive preparation for the treatment of various disorders.

Response to Arguments

Applicant's arguments filed 12/16/02 have been fully considered but they are not persuasive.

Firstly, the applicant argues regarding the 35 U.S.C. 102(b) rejection that, "Pfister does not teach a medicine storage layer comprising one or more medicines that permeate, dissolve, disperse or diffuse into a plasticized permeation control film which has been activated by moisture."

This argument has been fully considered but was not found to be persuasive. Pfister teaches a silicone pressure-sensitive adhesive transdermal drug delivery patch comprising five layers of a support body, reservoir for storing medicaments, a rate controlling membrane, adhesive and a release liner wherein drugs, such as cardiovascular agents and anti-anginal agents can be included. Fig. 3 of Pfister demonstrates a reservoir-type transdermal delivery device, which comprises a minimum of five layers from top to bottom. The transdermal device can include drugs, enhancers, excipients, such as polyols, surfactants and the like. The second layer includes a liquid reservoir, which contains the drugs, bioactive agents, etc. This reservoir is similar in means and effect of the medicine storage layer and serves an identical purpose as that of the medicine storage layer. The third layer, which is the rate controlling membrane layer acts as the rate controlling mechanism for the delivery of the drugs, excipients, etc from the reservoir and hence is similar in means and effects as the instant permeation controlling film since the bioactive agent passes from the reservoir through the rate controlling membrane. The applicant's attempt to distinguish over the prior art therefore is not seen as persuasive since the transdermal mechanism and device of Pfister achieves the same desired purpose as the applicant.

Secondly, the applicant argues, "Assuming the instant medicine storage layer were construed as being synonymous with the liquid reservoir of Pfister, Pfister does not describe a medicine storage layer that permeates, dissolves, disperses or diffuses into a plasticized permeation control film which has been activated by moisture."

This argument has been fully considered, but was not found to be persuasive since the permeation, dissolving, dispersing or diffusion of the medicine, which has been activated by moisture, is a future intended use. The examiner points out that a future intended use without structural limitation holds no patentable weight. Pfister teaches a reservoir layer, which functions to store or contain drugs, bioactive agents and the like and accomplishes a similar purpose as that of the instant medicine storage layer.

Next, the applicant argues, "Pfister does not provide a description of what a rate controlling membrane is and the term "rate controlling membrane appears to be merely functional."

This argument has been fully considered, but was not found to be persuasive since Pfister defines a rate controlling membrane at col. 8, lines 55-58, wherein Pfister teaches that a rate controlling membrane acts as the rate controlling mechanism for the delivery of the liquid drug(s), co-solvents, enhancers and excipients, from the reservoir.

The applicant argues, "Pfister does not describe the particular materials used for the permeation control films of Claims 2, 3 and 10-13."

The examiner points out that claims 2, 3 and 10-13 were previously withdrawn from consideration and are not included with the pending claims.

Next, the applicant argues, "There is no suggestion in Pfister of the superior properties of the present invention compared to conventional rate controlling membranes as is seen from the Declaration."

The Declaration has been fully considered by the examiner. However, the declaration was not found persuasive since Pfister achieves the same objective as the applicant, in that it provides for improved strength and stability without comprising beneficial and improved results.

Lastly, the applicant argues regarding the 35 U.S.C. 103(a) rejection of claim 9 over Mantelle, stating, "This patent neither discloses nor suggests the composition of claim 9."

This argument has been fully considered, but was not found to be persuasive since Mantelle teaches a bioadhesive composition, which comprises various drugs, such as cardiotonic drugs – dopamine and vasodilators, such as nicorandil and was relied upon for the teaching that the combination of such drugs can be formulated into bioadhesive pharmaceutical preparations.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns

February 28, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600